

**Assessment of the USEPA Region 6
Laboratory Certification Program for Drinking Water**

Conducted by the

**Office of Water
Office of Ground Water and Drinking Water
Technical Support Center**

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Introduction

The Office of Ground Water and Drinking Water (OGWDW) is required to review the EPA Regional Drinking Water Certification Programs annually including evaluation of the resources and personnel available to carry out the certification program. OGWDW's Technical Support Center (TSC) administers Annual Questionnaires and conducts triennial on-site Regional Laboratory Certification Program Assessments (RLCPAs). The EPA Region 6 RLCPA was conducted October 21- 23, 2015 at the EPA Region 6 Laboratory in Houston, Texas. The TSC review team included Carrie Miller and Glynda Smith from TSC, along with contract support from Laurie Potter of The Cadmus Group. See Attachment A for a copy of the agenda and Attachment B for a list of attendees at the opening and/or exit meetings during the review.

The Manual for the Certification of Laboratories Analyzing Drinking Water¹ (the Certification Manual) and Supplement 1² describes a process for the EPA Regions to oversee the certification of the Principal State Laboratory (PSL), or a PSL network of laboratories, in States that hold primacy by assuring each State has the capability to analyze all regulated drinking water contaminants per federal regulations [40 CFR 142.10(b)(4)]. The PSL laboratories may be certified by the Region, accredited through the National Environmental Laboratory Accreditation Program (NELAP), or recognized through a reciprocity agreement with another State laboratory certification program (LCP). If the PSL does not perform analyses for all regulated drinking water contaminants for a State, the State is required to institute a laboratory certification program (LCP) to certify commercial and municipal laboratories that analyze drinking water compliance samples. The LCP also may recognize a commercial or municipal laboratory that has been certified or accredited by another State through reciprocity. The EPA Regions are also responsible for assessing the adequacy of the State laboratory certification programs [40 CFR 142.10(b)(3)(i)]. Each Region holds primacy for all non-primacy States, including Tribal governments that oversee public water systems [40 CFR 141.2] and certifies/accredits or recognizes through reciprocity those laboratories analyzing such compliance samples.

In this report, TSC describes their assessment of the Drinking Water Laboratory Certification Program in EPA Region 6, including the Region's program to assess State Laboratory Certification Programs and to certify PSL. Commendations, findings, and recommendations are summarized.

1. Assessment Summary

a. Commendations:

1. Overall, the TSC Team noted a well-run LCP.
2. PSL audit files contained thorough notes. The PSL audit reports were concise yet reflected careful documentation of the quality of State SOPs, organizational charts,

¹ Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition, 2005, EPA 815-R-05-004.

² Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, Supplement 1 to EPA 815-R-05-004, June 2008, EPA 815-F-08-006.

observations or comments by method, and a discussion of general laboratory practices. The findings and recommendations sections were detailed.

3. Assessments and PSL audits were completed in a timely manner.
4. Proactive efforts were made to address difficulties with the Louisiana PSL through interim certification.
5. The LCPM clearly enjoys his relationship with EPA Region 6 States. The PowerPoint overview shared with States at the beginning of the PSL audit is a great tool to clarify the purpose of the visit. The annual QA conference is more substantial than the updates in many Regions and provides a good forum for discussion and opportunity to share information with the States. States routinely contact the LCPM with questions and receive timely responses.
6. PT results binders are very organized and reviewed, with any problems flagged.
7. In the last RLCPA, TSC had noted that States should have contracts or MOUs in place to address any capability or capacity concerns for the PSLs. The Region successfully encouraged States to put these vehicles into place.

b. Findings

1. The Region needs to review and update the SOPs for the SLCPAs and PSL audits: the EPA Guidance for Preparing Standard Operating Procedures (SOPs) recommends biannual or annual systematic review of these quality documents to ensure that the policies and procedures remain current and appropriate (EPA QA/G-6, EPA/600/B-07/001, Section 2.3). The current SOPs for conducting audits of the PSLs and state laboratory certification program assessments have not had documented review since 2011.

c. Recommendations

1. The filing system for SLCPA and PSL audit records could be improved. Suggestions include additional use of the shared network drive, including folders for each State and a folder which contains templates of what must be shared with the State before a program assessment or PSL audit; email accounts for each State; naming conventions for the files will make retrieval easier. Once the system is refined, it should be described in the SOPs.
2. The TSC Team recommends that the SOP's description of record-keeping practices be increased to at least 6 years while the EPA record-keeping policy is being appropriately interpreted.
3. TSC recommends that the Region expand the SLCPA SOP to document what items should be reviewed and discussed in the SLCPA report. An approach for more specificity and detail, especially in the findings, should be outlined. A robust report would:

- a. Specifically explain the Region's timeline for issuing reports, describe follow-up actions, and explain how the Region tracks/knows corrective action plans (CAPs) have been completed.
 - b. Assess resources needed for the State LCP. Potentially the Region could develop a rough algorithm to calculate the number of labs that can reasonably be audited per CO, and ask the State to explain underage/overage if its ratio is different.
 - c. For PT results: confirm whether sample results are released directly to the State and not just the laboratory (to prevent selective submission of results to the State); describe how results are received, stored, and tracked, e.g., electronically or manually; discuss what happens if there are 2 out of 3 PT failures.
 - d. Discuss State record-keeping practices and offer recommendations for improvements as needed.
 - e. Note if any laboratory has had its status downgraded from full certification.
 - f. Include an organizational chart for the State LCP and describe relationship with the State drinking water program.
 - g. Include list of labs audited by the State and the date of the State's most recent audit, as well as a list of active COs. Both items should be provided by the State prior to the SLCPA. These lists will help in the Region's assessment of whether the State has adequate staffing and resources to address its workload.
 - h. Describe the State's fraud detection procedures, including how peers/colleagues can report problems they detect and whether States have a process to evaluate lab integrity and report suspected fraud.
 - i. If third party assessors are used by NELAP-ABs, then the TSC Team recommends that documentation of their training and certification should be included in the report, as well as clear explanation of their role in the audit.
4. Region 6 should participate in PSL audits conducted by NELAP-ABs. It is valuable to have a prior arrangement with the NELAP-AB to clarify everyone's roles, e.g., observer versus auditor, and perhaps obtain written release and permission from laboratory that will be audited, as they pay for accreditation. It is important for Region 6 to observe assessments in Texas, since the Texas NELAP-AB (located in TCEQ) audits the Texas PSL (located in the Department of State Health Services). While these are different agencies with different reporting structures, EPA observation could reduce a perceived conflict of interest.
 5. Solicit input from the States on a draft agenda for the annual QA meeting with State COs; provide a teleconference line; and create meeting summaries and/or minutes.
 6. Develop a system to reconcile/track that PTs for each analyte and method are completed each year, such as a spreadsheet. For instance, Oklahoma has an electronic tracking system. The LCPM also could ask States to let him know when they order PT samples.

7. For the Louisiana Department of Health and Hospitals, track their timeliness for corrective action for their laboratory, including progress toward re-establishment of certification for radionuclides Audits by TSC may be suspended until corrective actions are complete.
8. The LCPM should follow up with States that do not respond fully to the Annual Questionnaire.
9. The Regional and State staff should attend CO refresher training if it has been more than five years since their last training.
10. Leverage additional resources to cover travel and FTEs needed to shadow State COs and NELAP assessors.

2. EPA Region 6 Lab Certification Program Overview

Regional Certification Authority (CA) has been delegated to James McDonald, the Assistant Regional Administrator for Management. R. Ray Clark is the Regional Laboratory Certification Program Manager (LCPM), and Marvelyn Humphrey is the alternate: both are authorized to lead lab audits in microbiology, radiochemistry, and chemistry (both organic and inorganic). Attachment C lists the 15 Regional Certification Officers (COs), their certification responsibility, and EPA training status. The CA and drinking water program staff are in Dallas, while the RLCP staff are located at the Regional Laboratory in Houston. Wes McQuiddy is the Regional Laboratory Director.

EPA Region 6 oversees the PSLs/PSL networks in five primacy States, including Arkansas, Louisiana, New Mexico, Oklahoma, and Texas. Louisiana and Texas are NELAP-Accreditation Bodies (NELAP-ABs), and Oklahoma is in the process of applying to become one. New Mexico conducts the laboratory audit and issues the report for the only tribal laboratory in the Region, the Sandia Pueblo laboratory. The report is reviewed by the Region, who issues the certification. Attachment D includes a table showing the number of certified laboratories in each State.

Ms. Humphrey is the Point of Contact representing Region 6 to the NELAP Accreditation Council, which ensures that the Region is well-informed about issues or concerns regarding coordination and compatibility between EPA certification and NELAP accreditation. The Region works closely with its NELAP-AB States.

Attachment E lists the State COs for each EPA Region 6 State, their areas of responsibility, and their EPA training status. The Certification Manual recommends COs attend refresher training every five years and training for numerous COs in EPA Region 6 States is outdated.

3. EPA Region 6 State Laboratory Certification Program Assessments

The EPA Region 6 SOP to conduct SLCPAs nominally meets all requirements of the Certification Manual. However, more detail is needed to fully explain the Region's process to conduct an assessment, as it refers to the Certification Manual which has limited detail on how to conduct a SLCPA. The EPA Region 6 SOP is a controlled quality document, and contains signature approval indicating that it has been both reviewed and approved by management. But, the SOP has not been

reviewed annually as recommended by the Certification Manual: the most recent review was dated September 20, 2011.

The Region forwards the TSC Annual Questionnaire to its States for the yearly review of the State laboratory certification programs. The State responses to the 2015 Annual Questionnaire are complete for all States except New Mexico.

The Region is current on all triennial SLCPAs for States audited and certified by Region 6. (The dates of the most recent SLCPAs for each State are reported in the table in Attachment D.) The SOP for the SLCPA describes the LCPM conducts interviews with State staff and reviews the State audit reports, CAPs, correspondence, data, tracking databases, and other audit-associated materials. However, the SLCPA reports and file notes do not reflect this thorough examination and do not cover all topics recommended in the Certification Manual. For instance, follow-up on findings was vague in reports and file records, and the TSC Team had to request additional information and interview the LCPM to determine whether an audit was closed out upon completion of corrective actions. The Region's files did not include proposed CAPs in all cases, or demonstrate that the State completed activities outlined in those plans. The LCPM explained that the Region asks if the corrective actions were completed at the next triennial review.

The SOP does not describe Regional participation with the NELAP Accreditation Bodies (NELAP-ABs) for assessments of NELAP-ABs. However, Region 6 chemistry COs participated with the NELAP-AB assessment team for Louisiana during 2014 and Ms. Humphrey observed the NELAP-AB assessment in Texas during 2015. EPA Region 6 is uncertain whether the Region will participate as an observer during the NELAP-AB assessment of Oklahoma as a NELAP-AB.

Prior to the SLCPA, the State provides the Region with a list of labs audited by the State, the date of the lab's most recent audit, and a list of active COs. No detail from these lists was included or synthesized in the SLCPA reports, and the SLCPA report did not indicate whether State audit reports were timely, or whether the State has adequate resources to run its program.

During the SLCPAs, the Region usually does not shadow State COs as they observe analysts during audits of labs within the States. The Region did join the NELAP-ABs to observe analysts during the lab assessments in Louisiana and Texas; however, COs from the other 3 states were not observed during those state lab audits.

EPA Region 6 holds an annual Quality Assurance meeting for all State COs each year in Dallas, inviting speakers and presenting drinking water program and laboratory certification updates.

The Region does not have a formal fraud reporting and ethics program for drinking water and fraud is not addressed in the Region's SOP; however, the LCPM attended fraud training and took pictures of examples which he has shared with laboratory directors in the Region 6 States. In addition, he informally presented examples or tests from the ethics training course to the laboratory directors. The TSC Team stressed the importance of cultivating a culture of ethical behavior.

The Region 6 LCP staff coordinates with the drinking water program office when needed, but the program staff does not attend SLCPAs or PSL audits. The LCPM often communicates with the State LCPMs by phone and email to respond to questions or seek information. The alternate LCPM, and the TSC team, encourage him to follow up phone conversations with an email for documentation.

4. EPA Region 6 Principal State Laboratory Audits

The EPA Region 6 SOP to conduct audits of the PSLs is a thorough and controlled quality document, but, like the SOP for SLCPAs, it is overdue for review. It was last reviewed in 2011.

On May 4, 2015, the TSC Deputy Director issued a memo to the Regions confirming that drinking water certification must be specific to both the method and the regulated analyte. This requirement is not presently in the Region's SOP. The SOP also does not indicate a process for tracking certification status for State PSLs or PSL networks or a process to track receipt of proficiency testing (PT) results from State PSLs. The SOP also does not include steps to document the PSL capability and capacity to analyze all regulated drinking water contaminants.

In their responses to the TSC Annual Questionnaire, which was forwarded to the Region 6 States by the LCPM, some States did not identify the process followed if a PSL failed to accurately analyze two PT samples.

Texas Commission on Environmental Quality (TCEQ), which is the Texas NELAP-AB, audited the Texas PSL which is in a separate State agency, the Department of State Health Services. Two laboratory assessments for labs performing drinking water work were conducted by assessors who did not attend the EPA CO training course. Drinking water certification audits need to be performed by auditors with the proper training: the evaluation team listed this as a priority.

The Region's audits of PSLs are current and the reports are thorough and timely. The TSC Team found CAPs and correspondence between the Region and laboratory directors regarding the reports, but there is no specific tracking system used in the Region to track implementation of corrective actions or close-out of the audits.

EPA Region 6 documented critical findings in the 2 most recent Louisiana PSL audit reports. The Region extended the timeline for performing a chemistry/microbiology audit of the Louisiana PSL for 3 years, as the laboratory addressed shortcomings and facility issues during its relocation to a new site. The laboratory was granted interim certification over this timeframe. The TSC Team confirmed that this was an appropriate approach, as long as the laboratory can pass PT samples for which they had interim certification and the Region does not give provisional or full certification until the laboratory has addressed identified issues, e.g., broken equipment, software issues, and inadequately trained analysts. Without a defined tracking process documents planned and implemented corrective actions, the Region may struggle to confirm that Louisiana's critical QA failures are addressed.

The Sandia Pueblo laboratory was downgraded by New Mexico to provisional certification because of two findings identified in the September 2012 audit. The Region supplied a letter showing the corrective actions had been implemented, but again, there is no formal process to track these corrections. In this instance, follow-up should be performed by both New Mexico and Region 6, because the Region has direct implementation authority over tribal programs, but has agreed along with the tribe that the State may conduct the audits and write the report.

The Region carefully reviews and organizes PSL PT samples in binders by State, but no formal tracking system is in place to determine if PTs are missing. The LCPM sometimes confers informally by phone with State laboratory directors to determine when PT samples will be sent. Lab certificates note that certification can be withdrawn if the laboratory fails in its analyses of PT samples.

The Region has not been able to shadow or observe State COs as they audit labs, due to resources, and, the LCPM has been conducting inorganic laboratory audits as well as the SLCPAs to reduce costs, which imposes additional workload and may be unsustainable without assistance from the Regional COs. Resource constraints are a concern. The Region foresees increased costs for both travel and staff time to jointly audit the Sandia Pueblo laboratory in New Mexico and continue participation in the TX NELAP audit of the Texas PSL.

5. Records Management

The SOPs for the SLCPAs and PSL laboratory audits indicate that records are kept on-site for a period of approximately three years, then forwarded to the Houston, Texas records center. During interviews, EPA Region 6 confirmed it retains records for three years, and then disposes of the records. Currently, the Certification Manual recommends that records be kept for 6 years, but the EPA's Office of Information has been contacted to inquire whether Schedule 10-16 (c) for a 10-year retention policy may be more appropriate.

The SOPs do not specify how records are maintained on-site. The TSC Team noted that records are kept in the LCPM's office, but not organized in a way that colleagues can easily understand the filing system. Electronic materials are kept on the LCPM's computer. Many materials and responses are communicated by email to the LCPM and alternate LCPM. The Region's policy for electronic materials is not discussed in the SOPs.

Attachment A
Agenda: EPA Region 6 Laboratory Certification Program Assessment
October 21-23, 2015

Wednesday, October 21

Arrive at EPA Region 6 laboratory by 1:00 p.m.

1:15 – 1:30 Opening Meeting

1:30 – 5:00 Review EPA Region 6 records

Thursday, October 22

Arrive at EPA Region 6 laboratory by 9:00 a.m.

9:00 – Noon Continue record reviews

Noon – 1:00 Lunch

1:00 – 5:00 Continue record reviews

Friday, October 23

Arrive at EPA Region 6 laboratory by 9:00 a.m.

9:00 – 11:00 Complete final record reviews and compile notes for closing meeting

11:00-11:30 Closing meeting

11:30 – Noon Open time for questions

Attachment B
Attendees at Meetings for the October 2015 EPA Region 6 RLCPA

	Participant	Program	Role	Meeting
1.	Marvelyn Humphrey	EPA Region 6	Associate Branch Chief	Opening and exit meetings
2.	Rick McMillin	EPA Region 6	Deputy Lab Director	Opening and exit meetings
3.	R. Ray Clark	EPA Region 6		Opening and exit meetings
4.	Carrie Miller	EPA OGWDW/TSC	TSC Lead Assessor Assessment Team	Opening and exit meetings
5.	Glynda Smith	EPA OGWDW/TSC	TSC Assessment Team member	Opening and exit meetings
6.	Laurie Potter	The Cadmus Group	Contractor Assessment Team member	Opening and exit meetings

Attachment C

Area of Responsibility and Training Status of Regional Laboratory Certification Program Personnel

Title	Name	Area(s) of Responsibility*	Year Passed EPA CO Course	Year Last Audited EPA CO Course	Portion of FTE* Allocated to Laboratory Certification Program
Regional Certification Officer	Abel Euresti	Microbiology	1989	2009	
Regional Certification Officer	Meredith Clarage	Organic	2000		
Regional Certification Officer	Ray Clark	Inorganic	2000	2009	
Regional Certification Officer	Kumar Devabhaktuni	Inorganic	2010		
Regional Certification Officer	Ray Flores	Organic	1999		
Regional Certification Officer	Nick Gannon	Organic	2005		
Regional Certification Officer	Diane Gregg	Organic	2000		
Regional Certification Officer	Johnson Matthew	Inorganic	2006		
Regional Certification Officer	Neal Nguyen	Organic, Inorganic	2005		
Regional Certification Officer	Ed O'Neill	Organic	1999		
Regional Certification Officer	Rebecca Quinones	Microbiology	2006		
Regional Certification Officer	Tim Sanders	Inorganic	1999		
Regional Certification Officer	David Stockton	Inorganic	1984		
Regional Certification Officer	Kenneth Stevens	Organic	2003		
Regional Certification Officer	Lisa Wool	Organic	2002		

* Specify Chemistry, Microbiology, Radiochemistry, *Cryptosporidium*, etc.

Attachment D

Primacy State Drinking Water Laboratory Certification/Accreditation Programs

Date of Last Assessment & Number of Laboratories In- and Out-of-State

State	Number of Laboratories Certified/Accredited In State (Out of State)							
	Agency	Assessor	Date of last SLCPA	Date of last signed certificate/report	Chemistry	Microbiology	Radiochemistry	<i>Cryptosporidium</i>
AR	Arkansas Department of Health	EPA Region 6	Sept. 10-13, 2012	February 15, 2013	0 (0)	5 (0)	0 (0)	0 (0)
LA	Louisiana Department of Health & Hospitals	EPA Region 6	July 2009	October 16, 2015	0 (0)	13 (0)	0 (0)	0 (0)
LA	Louisiana Department of Health & Hospitals	TNI-NELAP AB including EPA Region 6	April 8-9, 2014	August 20, 2014	5 (22)	0 (0)	1 (7)	0 (0)
NM	New Mexico Scientific Laboratory Division	EPA Region 6	February 20, 2014	March 25, 2014	0 (0)	30 (0)	0 (0)	0 (0)
NM	New Mexico Environmental Division Drinking Water Bureau	EPA Region 6	February 19, 2014	March 25, 2014	2 (27)	29 (2)	1 (8)	0 (0)
OK	Oklahoma Department Environmental Quality	EPA Region 6	October 1, 2012	July 15, 2013	16 (2)	16 (2)	1 (1)	1 ² (0)
TX	Texas Commission on Environmental Quality	TNI-NELAP AB including EPA Region 6	June 16-18, 2015	Pending	41 (35)	95 (9)	1 (15)	0 (0)

Attachment E: Area of Responsibility and Training Status of Certification Officers in Primacy States

Name/Affiliation of State CO	State	Area(s) of Responsibility	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Mathew Bradke-ADH	AR	Chemistry, Microbiology	2008	2013 2013
Cathy Moore-ADH	AR	Microbiology	1984	1999
Eve Berry-ADH	AR	Microbiology	1998	2013 2013
Benjamin Jefferson-ADH	AR	Chemistry	2005	Not applicable
Alindria Carroll-ADH	AR	Microbiology	2014	
James Baldwin-ADH	AR	Microbiology	1999	
Dorothy Ferguson-ADH	AR	Chemistry	2005	
David Duke-ADH	AR	Chemistry	2005	
Tim Troup-ADH	AR	Chemistry, Microbiology	1995	
David Boucher-LDHH	LA	Chemistry	2011	
Renee Pettito-LDHH	LA	Microbiology, Cryptosporidium	2013, 2015**	
Donnell Ward-LDHH	LA	Chemistry,	2009	
Gary Oty-NMSLD	NM	Microbiology	2005	
Michael Trujillo-NMSLD	NM	Chemistry	2005	
Chet Markham- NMSLD	NM	Chemistry	2008	
Erica Swanson- NMSLD	NM	Microbiology	2012	
Kristin Cochran- NMSLD	NM	Chemistry-organic,	2013	
David Caldwell- ODEQ	OK	Chemistry, Microbiology	2001, 2006	
Mikeshell Riley- ODEQ	OK	Chemistry	2014	
ND Kaku-TCEQ	TX	Chemistry-organic, Microbiology	2014, 2013	
Ruth Wedig-TCEQ	TX	Chemistry, Microbiology	2009, 2010	
Sam Morehead-TCEQ	TX	Chemistry	2015*	
Steve Gibson-TCEQ	TX	Chemistry, Microbiology	1999, 2014	
Jessica Akins-TCEQ	TX	Microbiology	2015*	
Donnie Cantu-TCEQ	TX	Chemistry	2015**	
Travis Bartholomew-TCEQ	TX	Chemistry, Microbiology	2014, 2014	
John Gumper-TCEQ	TX	Chemistry, Microbiology	2014, 2014	
Ronald Winter-TCEQ	TX	Chemistry, Microbiology	2015*,2015**	
Anthony Francis-TCEQ	TX	Chemistry, Microbiology, Cryptosporidium	2014, 2014 2015**	
Michael Shepherd-TCEQ	TX	Chemistry, Microbiology, Cryptosporidium	2012, 2013, 2015**	
Mei Beth Shepherd-TCEQ	TX	Chemistry, Microbiology, Cryptosporidium	2012, 2013, 2015**	
Michael Hintz-TCEQ	TX	Chemistry	2015*	